

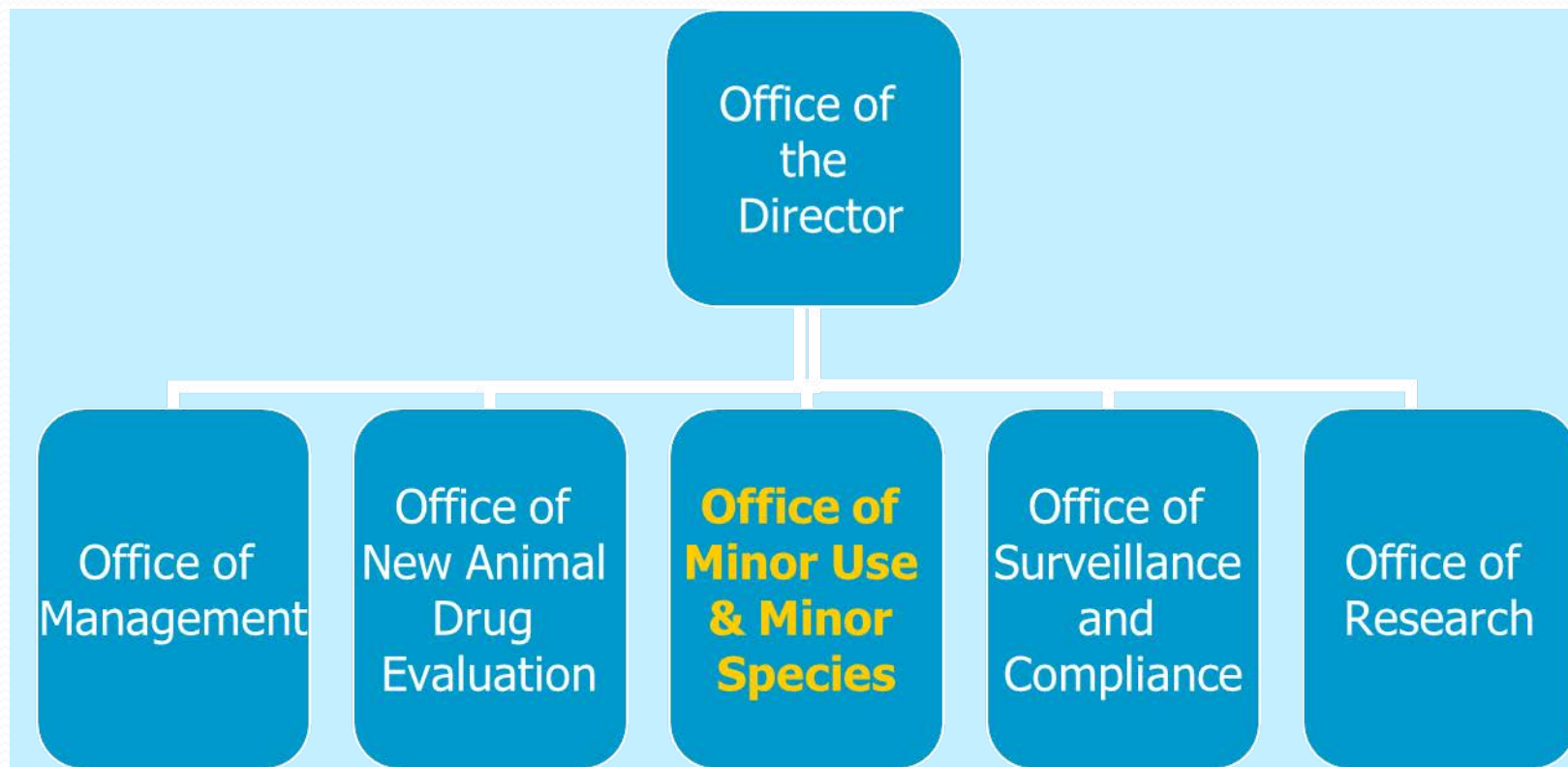
Programs for Minor Uses and Minor Species

FDA/CVM/OMUMS

FDA 101

2020

Center for Veterinary Medicine



The Office of Minor Use and Minor Species Animal Drug Development (OMUMS)



OMUMS Personnel



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Background:

What are minor uses and minor species?



Definitions

Minor Species-



**ALL animals
other than
humans that
are not
major
species**

Major Species:

Dogs

Cats

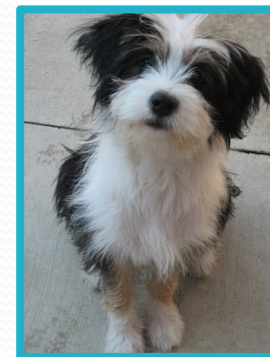
Horses

Cattle

Pigs

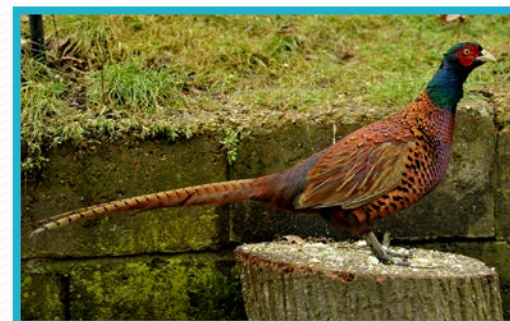
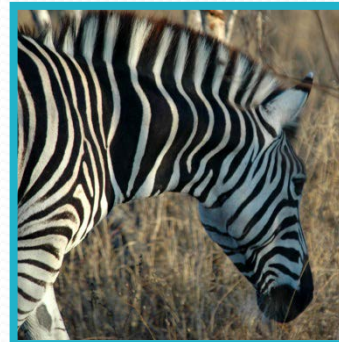
Chickens

Turkeys



Some minor species:

- ❖ Zoo animals
- ❖ Ferrets, guinea pigs
- ❖ Sheep, goats
- ❖ Honeybees
- ❖ Pheasants
- ❖ Fish



Minor Use in a Major Species



The intended use of a drug in a major species for an indication that occurs infrequently and in only a *small number* of animals annually in the United States

What are the Small Numbers?



- 50,000 Horses
- 70,000 Dogs
- 120,000 Cats
- 310,000 Cattle
- 1,450,000 Pigs
- 14,000,000 Turkeys
- 72,000,000 Chickens

The Problem (\$\$\$)



Minor species/use markets are too small to be economically worth a drug company's investment in an FDA drug approval

The MUMS Act of 2004

- ❖ Law intended to make more drugs legally available to treat minor species and minor uses
- ❖ Provides innovative ways to help drug companies overcome financial hurdles to getting these drugs approved
- ❖ Allowed for the establishment of OMUMS to implement provisions of the law



Intent of the MUMS Law

- ❖ To provide needed incentives to encourage drug approval. *Designation*
- ❖ To allow early marketing to recoup investment costs. *Conditional Approval*
- ❖ To provide alternate legal means to market drugs in some cases. *Indexing*
- ❖ To establish an Office to administer some of these programs and provide outreach to stakeholders. *OMUMS*



MUMS Drug Designation

- ❖ Designation is a “status” that qualifies a sponsor for incentives that facilitate drug approval
- ❖ Comparable to human “orphan” drug status
- ❖ Only one product for the same drug/dosage form/intended use may be designated- unique
- ❖ Currently, there are 153 MUMS designations (117 minor species, 36 minor uses). Includes fish and shrimp, pheasants, quail, honey bees, small ruminants, dogs, horses, cattle, and more



MUMS Drug Designation

Designation incentives include:

- ❖ Exclusive marketing rights for 7 years after approval to protect against direct competition
- ❖ Eligibility for grants up to \$250,000 each

FDA/CVM/OMUMS has funded 61 studies totaling \$4.9 million since FY2009 to support the approval of MUMS-designated drugs

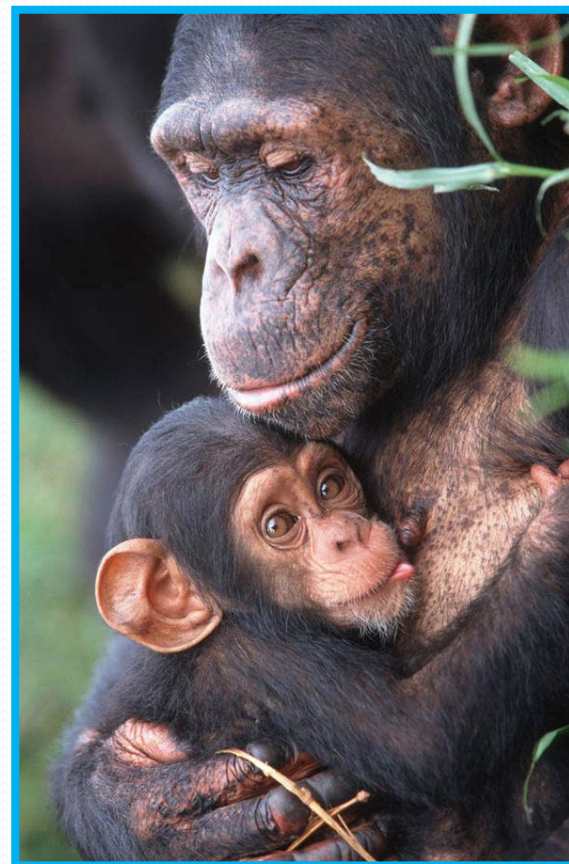
Conditional Approval

- Allows early marketing to get some return on investment for sponsors
- Drug must meet all approval requirements except for effectiveness
- Sponsor has up to 5 years (contingent upon annual renewals) to complete effectiveness section to receive a full drug approval



The Index of Legally-Marketed Unapproved New Animal Drugs for Minor Species (the Index)

- Alternate legal means to market drugs in some cases
- Products that cannot practically use the drug approval process – animals too varied, too inherently valuable, too rare, etc.
- Examples are: drugs for zoo animals, lab animals, pet birds, ornamental fish, and pocket pets



Indexing

- **Alternative to FDA review process for drug approval**
- **Applies to non-food (or early life stages) minor species only**
- **Based on report of an outside expert panel (FDA must agree)**
- **14 products indexed so far: ornamental fish, elephants, rhinos, ferrets, rats, mice, raptors, pet birds and more!**



Responsibilities of OMUMS

- ❖ Designation of MUMS drugs
- ❖ Administer grants for Designated projects
- ❖ Indexing
- ❖ Conditional Approval (eligibility)
- ❖ Minor Use determinations (User fee waivers)
- ❖ Liaison to other government programs (USDA MUADP)
- ❖ Stakeholder outreach



Minor Use Animal Drug Program (MUADP)

- USDA program to fund studies in support of drug approval for minor species of agricultural importance
- OMUMS provides a liaison to the program to guide projects through the approval process
- Program has supported 29 approvals so far



Our Office (OMUMS)

- ❖ OMUMS is not responsible for the drug approval process. MUMS drugs go through the same approval process by the Office of New Animal Drug Evaluation (ONADE) as any other drug
- ❖ OMUMS facilitates the process and manages incentive programs for MUMS drugs



For Further Information...

<https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/default.htm>

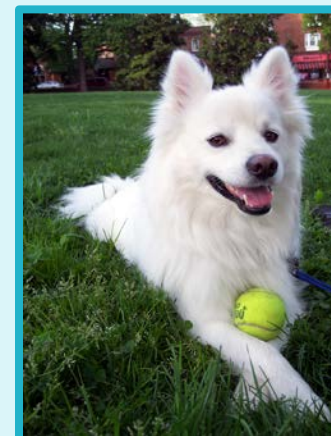
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Questions?

